The Immunization Encounter: Critical Issues satellite broadcast. Originally broadcast June 27, 2002

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ATKINSON:
Welcome to The Immunization Encounter: Critical Issues. We're coming to you live from the Centers for Disease Control and Prevention in Atlanta, Georgia. I'm William Atkinson and I'll be your host for this live satellite broadcast.

Today's broadcast is the first for the National Immunization Program in 2002, and the thirty first we've produced since 1995. It's unique in that we won't be talking very much about vaccines or vaccine recommendations. Instead, we will concentrate on many of the OTHER immunization related issues that you face every day in your office or clinic, such as vaccine storage and handling, vaccine administration, and screening for contraindications.

We have two instructors for today's program. Donna Weaver is a nurse educator in the National Immunization Program at CDC. Ms. Weaver has a masters degree in nursing, and has been working in immunization programs since 1996. Our second instructor is Dr. Judy Schmidt. Dr. Schmidt is a Public Health Educator in the National Immunization Program at CDC. She holds degrees in nursing and education and has been with the National Immunization Program since 2000.

In this program we will address issues that immunization providers encounter every day. We will begin with a discussion of activities that should occur before your patient arrives. In this section we will concentrate on vaccine storage and handling, and preparing for an emergency. The second section of the program will cover activities that should occur DURING the immunization encounter. In this section we will discuss parent and patient education and the use of Vaccine Information Statements, screening for contraindications and precautions, and vaccine administration. In our third section, we will discuss post encounter activities, including documentation and record keeping, the Vaccine Injury Compensation Program, and the Vaccine Adverse Event Reporting System.

Let's look at the objectives for this program. After this program, we hope you will be able to do these things and much

more: describe two recommended activities in preparation for the immunization encounter. List critical issues involved in patient and parent education, screening, and vaccine administration during the immunization encounter, and: describe recommendations and responsibilities related to post- vaccination care and record keeping.

Our program will begin with a discussion of pre encounter activities right after this pause.

[UNSCRIPTED VIDEO PROMO]

ATKINSON:
This program is divided into 3 main sections: the pre encounter phase, before the person arrives; the encounter phase, when the person is in the office; and the post encounter phase, after the person leaves the office. For each of these immunization encounter phases, we've prepared a checklist of activities that should be part of your routine during that phase. We will then discuss some of these activities in detail. Donna, would you review the pre encounter checklist for us?

WEAVER:
Yes, Bill, I will. There are many activities that should take place BEFORE the patient arrives at your office. Most of these activities are not specific for one patient, but are components of a good immunization delivery system in your office or clinic. Let's go through some of them.

One of the most important pre encounter activities for your office is staff training and education. Competency- based orientation and continuing education for staff are critical to providing safe, effective and caring immunization services. Training and education is not a one shot event but a systematic ongoing program.

Patient reminders are one of the most effective strategies for raising and maintaining high immunization coverage levels. Call or send patients a note to remind them about their upcoming appointment and remind them to bring their immunization card. Make your life easier by participating in an immunization registry if one is available in your area.

Adequate clinic supplies and patient education materials. Check your inventory first thing in the morning. Be sure that you have adequate materials and supplies on hand before your clinic day begins. You certainly don't want to run out of syringes- or

vaccine- before the day is over.

Patient record pre-screening for recommended immunizations. We strongly recommend that medical records be screened BEFORE the patient arrives to assess the need for recommended immunizations. You should do this even if the patient is scheduled for something other than immunizations. This will help you to avoid a missed opportunity and can save time on the appointed day.

Every person to whom you administer a dose of vaccine is dependent on your vaccine storage and handling procedures. There is very little room for error when it comes to proper storage of your vaccine supply.

Likewise, every person to whom you administer a dose of vaccine is potentially dependent on your offices' emergency preparedness - the procedures and protocols you have in place in the unlikely event of a medical emergency, such as an allergic reaction.

These last two activities - vaccine storage and handling, and emergency preparedness, are critical components of good immunization practice. We would like to discuss both of them in ore detail, beginning with vaccine storage and handling.

ATKINSON:
Proper storage and handling procedures are critical to a safe and effective vaccination program. Inattention to vaccine storage conditions can lead to damaged vaccine and reduced protection.

Most live vaccines, in particular MMR, varicella and yellow fever vaccines, are sensitive to light and increased temperatures. Inactivated vaccines can be damaged by exposure to freezing temperatures. Some products may show physical evidence of altered integrity, like clumping in the solution that doesn't go away when the vial is shaken. But other vaccines may look perfectly normal, giving no indication of loss of potency.

All staff working with vaccines in an office or clinic setting should be familiar with proper storage and handling to minimize the risk of damage to your vaccine supply. During this segment we will cover general guidelines for proper vaccine storage and handling. Specific storage and handling recommendations for each vaccine are available in the manufacturer's package insert and several other resources, which will be included on the resource web page for this broadcast. Judy?

SCHMIDT:

Thanks, Bill . There are few immunization issues more important than the appropriate storage and handling of your vaccine supply. This is also one of the most common vaccine delivery problems that we encounter at the National Immunization Program. A vaccine storage or handling failure can affect large numbers of your patients, and result in embarrassment, expense, and potential liability for your practice.

Every facility that stores vaccines should develop and maintain a detailed written protocol on vaccine storage and handling. This protocol should include information for accepting vaccine deliveries and guidelines for storage and handling. Each facility should assign one person primary responsibility for ensuring that vaccines are carefully handled in a safe, documented manner. Since no one works every single day, a back-up person should also be designated. All office staff working with vaccines should be familiar with storage and handling guidelines. Post temperature guidelines for vaccines on or near the refrigerator and freezer where vaccines are stored.

Your responsibility for proper vaccine storage and handling begins the moment the vaccine arrives. Vaccine shipments should be examined on arrival. Examine the shipping container and its contents for any evidence of damage during transport. Cross-check the contents with the packing slip to be sure they match. Finally, check the shipment date to determine how long the package was in transit to you. If the interval between shipment from the supplier and arrival of the product at your office was more than 48 hours, it could mean the vaccine has been exposed to excessive heat or cold that might alter its integrity.

Each shipment should be recorded on an inventory log. This log should include the name of each vaccine; the number of doses for each vaccine received; the date it was received; the condition of the vaccines upon arrival; the name of the vaccine manufacturers; the lot numbers; and the expiration dates for each vaccine

If there are any discrepancies with the packing slip or concerns about the vaccine shipment, store the vaccine under proper conditions and mark, "Do NOT Use" until the integrity of the vaccine is determined. You will then need to contact the manufacturer or your state immunization program for further guidance. Who you contact will depend on who shipped the vaccine to you and on your agency or state policy.

In order to store vaccines correctly in your office, you must

have the right equipment. Vaccines must be stored in a properly functioning household- or commercial- style refrigerator- freezer unit. The refrigerator and freezer compartments must have separate doors. This is particularly important if you stock varicella vaccine.

We discourage the use of small single door refrigerators like this. This type of unit may be OK for storing small quantities of inactivated vaccines, if the refrigerator compartment can maintain a constant temperature. But the freezer compartments of these units are incapable of maintaining temperatures cold enough to store varicella vaccine, so they are totally unacceptable for offices that use varicella vaccine. You have a lot of money invested in your vaccines. So do the right thing, and invest in a quality refrigerator freezer to store them in. Use the dorm refrigerator to store your salads and snacks.

The refrigerator and freezer compartments should have their own thermometers. The thermometers should be placed in the central part of the storage compartment, not against the wall. There are several types of thermometers you can use. Here are 3 types of certified calibrated thermometers. The thermometer on the left in biosafe liquid is available for refrigerators and freezers. The one in the center is a continuous graphic thermometer, which records temperatures on graph paper. The thermometer on the right records the upper and lower extremes of temperature during the observation period. This is referred to as a minimum- maximum thermometer. These thermometers provide a means of establishing if vaccines have been exposed to potentially harmful temperatures. Get the best thermometer you can afford.

Temperature readings should be taken and recorded on a temperature log like this, twice each day, once when the office or clinic opens and again at the end of the day. Also, the back-up person should review the log on a weekly basis to assure proper temperature recording. The date and time of any mechanical malfunction or power outage should also be noted. Some temperature logs have a place to record this information on the back of the temperature log. Temperature logs should be kept on file for a minimum of three years.

One very important point to remember is that it's not enough to just record the temperature of the refrigerator and freezer units twice daily. If a temperature outside of the recommended range is found, then IMMEDIATE action should be taken to correct the problem. It may be a problem that can be solved easily, such as a door that was left open, or a unit was unplugged. On the other

hand, there may be a more serious problem with the unit- after all, all refrigerators eventually fail. It could also be a power failure or some type of emergency or disaster situation that will require alternative storage for the vaccine until the situation is corrected. It's very important that staff know whom to contact in case of a malfunction or disaster. If the problem is short- term, usually 2 hours or less, you can probably maintain the temperature in the unit by adding ice or ice packs and keeping the door closed. If there is an extended period of time before the situation can be corrected, then you should move the vaccine to another cooling unit.

It's a good idea to have an agreement with another clinic, hospital or agency where you can store your vaccine in an emergency. If the vaccine can be moved to this site within 30 minutes, it can be transported in insulated containers or coolers. If the location is more than 30 minutes away and you have a large quantity of vaccine, you should consider renting a refrigerated truck to transport your vaccine. Also, remember whenever there is a question about the integrity of the vaccine, contact the vaccine manufacturer and/or your state immunization program for guidance.

The BEST recommendation we can make is to take precautions to PREVENT problems. In addition to the twice daily monitoring of the refrigeration unit, install a plug guard or safety lock plug to reduce the chance of someone inadvertently unplugging the unit. Post warning signs above the plug and on the storage unit to remind staff not to unplug the unit. Label fuses and circuit breakers with information that clearly identifies power to the vaccine storage unit, and the immediate steps to be taken if power is interrupted. Install a temperature alarm that is audible and, if possible, connected to a remote or automated telephone system.

Here's a simple technique that will tell you if your freezer has thawed. Fill a plastic cup with water, freeze it, and place a penny on TOP of the frozen ice in the cup. Place the cup in the middle of the freezer compartment. Check the placement of the penny each morning when you record the freezer temperature. If the penny is IN the ice you know the freezer temperature was not maintained while the office was closed. You will need to talk to the manufacturer or state immunization program before using any of the vaccine stored in the freezer.

Another point to remember is to learn from previous situations or mistakes. Whenever there is a violation of the vaccine handling

protocol or another vaccine storage problem, document the occurrence. Use the experience as a learning opportunity for all clinic or office personnel and when training new staff so that a similar situation can be avoided in the future. Donna, will you tell us more about storing vaccines?

WEAVER:
Thank you Judy. It's critical that your vaccine supply be stored carefully. All vaccines, with the exception of varicella and yellow fever vaccines, should be stored in the refrigerator section.

The refrigerator must maintain a temperature between 35 and 46 degrees Fahrenheit. That's 2 to 8 degrees Celsius. We suggest that you set your refrigerator temperature to an average of 40 degrees Fahrenheit, or 5 degrees Celsius. This will allow your refrigerator to fluctuate within the recommended range of 35 to 46 degrees Fahrenheit. Your freezer must maintain an average temperature of 5 degrees Fahrenheit, or minus 15 degrees Celsius or colder. This temperature is necessary to assure proper storage of varicella vaccine. Lyophilized, or freeze dried, vaccines are in a powder form and must be reconstituted before use. Vaccine diluents can be stored in the refrigerator or at room temperature. Do NOT freeze vaccine diluent.

Vaccine should be stored in the middle of the refrigerator compartment away from the walls and coils. This allows air to freely circulate around and through the vaccine stacks and provide even cooling to all stored vaccine. To avoid confusion, the vaccine should be stacked in rows with vaccine of the same type. Bottles or jugs of water stored next to the walls or on an empty shelf will help maintain an even temperature in the refrigerator compartment.

Vaccine stored in the freezer compartment should also be located in the center of the compartment and away from sides of the unit. Ice trays or ice packs can be used in the freezer to help maintain an even temperature.

Never store vaccines in the door of the refrigerator or freezer, or on the bottom or near peripheral areas of the unit. There is greater temperature fluctuations in these areas, and temperature fluctuations are bad for vaccine.

Check and rotate vaccine stock weekly so that vaccines with the shortest expiration dates are in the front to be used first. If the expiration date on the vial is identified only as month and

year, the vaccine does not expire until the LAST day of the month indicated on the vial.

Expired vaccine - even if only one day after the expiration date- should NEVER be administered. Promptly remove expired vaccine from the refrigerator or freezer and dispose of it appropriately. If the expired vaccine is VFC vaccine, you should contact your state immunization program so that the expired vaccine can be accounted for.

Keep opened vials of vaccine in a tray, so that they are readily identifiable. Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.

Pediatric DT, adult hepatitis B, influenza, meningococcal, pneumococcal polysaccharide, IPV, Td and tetanus toxoid are manufactured in multi-dose and single dose vials. A multi dose vial of vaccine contains a bacteriostatic agent, usually thimerosal. This vaccine can be used until the date of expiration unless it becomes visibly contaminated. Single dose vials do not contain a bacteriostatic agent and are meant for one time use only. Once opened, they must be discarded after 24 hours.

Once a lyophilized vaccine has been reconstituted, the clock is running. Reconstituted vaccines must be used within a specified time frame or they must be discarded. Varicella and ActHIB brand of Hib vaccine must be used within 30 minutes. Yellow fever vaccine must be used within one hour of reconstitution. MMR must be used within 8 hours, and PedvaxHIB must be administered within 24 hours. Vaccines reconstituted beyond these limits should NOT be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration.

Varicella vaccine that has not been reconstituted can be stored in the refrigerator compartment for up to 72 hours. If not used within 72 hours at refrigerator temperature, it must be discarded. Varicella vaccine should not be refrozen.

We are often asked about prefilling syringes, or drawing up vaccine into syringes in advance of the need for it. We STRONGLY discourage this practice. Loading vaccine into syringes before you are ready to use it increases the risk for medication errors, vaccine contamination, and vaccine wastage. When time and staff are limited and demand is high, most commonly- used vaccines are available in prefilled syringes from the manufacturer. Manufacturer prefilled syringes are prepared under

sterile conditions that meet standards for proper handling and storage and they are individually labeled. Varicella, MMR, and yellow fever vaccines must NEVER be drawn up ahead of time. But there may be situations in which a single vaccine is going to be administered- such as a large influenza campaign- and manufacturer's prefilled syringes are not available. In these situations, each person giving injections may choose to prefill a few syringes shortly before administration.

In keeping with nursing medication administration guidelines, we recommend that the person who prepares the medication should be the same person who administers the medication. We recommend that any prefilled syringes should be properly stored and should be used on the same day they are filled. Label each syringe carefully, and keep the filled syringes cool.

Vaccines should always be stored in the refrigerator or freezer until they are needed. Even if you anticipate using vaccines throughout the day, do not leave them sitting out on a medicine tray or counter.

If your clinic situation permits, open only one vial, or box, of a particular vaccine at a time to control vaccine usage and allow easier inventory control. We also recommend that all opened vaccine vials be kept in a tray in the refrigerator separate from other medications and biologics to avoid medication errors. Do NOT store food and beverages in the same refrigerator or freezer with vaccines. This practice leads to more frequent opening of the unit and greater chance for temperature instability and excessive exposure to light. It's advisable to keep MMR, varicella and yellow fever vaccines in their boxes with the top on until ready to use to avoid unnecessary light exposure. If other medications and biologics MUST be stored in the same unit with vaccine, then store the vaccines on a different shelf. This will help reduce the chance of a medication error, or contamination of the vaccine in the event the other medications or biologics spill.

Occasionally vaccines must be transported between clinics or administered at sites where there is no permanent storage unit. In these situations, you must still maintain appropriate storage temperatures. Always use insulated containers for vaccine transport. A thermometer must be placed in each container so that the temperature can be monitored and documented hourly. Craft paper, newspaper, or bubble wrap should be used to keep the vaccine from coming in direct contact with the ice and inadvertently freezing. Varicella vaccine can only be transported

and temporarily stored using dry ice. Other vaccines should be stored in separate containers with regular ice. And remember NEVER touch dry ice without wearing heavy-duty gloves and eye protection.

Inventory control is an important quality control measure. Conduct a monthly vaccine inventory. This helps you avoid running out of vaccine or over-ordering. If you work in a satellite clinic, avoid stocking excessive amounts of vaccine because of the possibility of a power failure. Whenever conducting a monthly inventory, check the expiration dates. Rotate your stock to assure that the vaccine with the earliest expiration date is being used first to minimize waste. NEVER use expired vaccine. If a dose of expired vaccine is given by mistake, the dose should be repeated.

Sometimes vaccine just seems to disappear. To avoid the inappropriate removal of vaccine, limit access to the vaccine storage refrigerator to authorized personnel. When the unit is not being used, keep it closed and locked.

We recently had the opportunity to talk with Jean Popiak, one of our vaccine management experts here at the National Immunization Program. We asked Jean to share with us some of the most common errors in vaccine storage and handling.

POPIAK:
As a state vaccine manager and now with the National Immunization Program, I have seen my share of costly vaccine management errors. Here is my Top Ten list of vaccine storage and handling no-no's, boo-boo's, transgressions, errors, offenses, violations, treasonistic acts, and absurdities.

Number 10: Only one person in the office is responsible for vaccine. Now let's face it, everyone gets sick or takes a vacation. It's important to train a backup person to learn your job, specifically when it comes to storage and handling of vaccines. Your backup should be well versed in recording refrigerator and freezer temperatures and recording them properly. Your backup should also know what to do in case of an equipment problem or power outage, but more on that later.

Number 9: Vaccine stored in the wrong part of the refrigerator like the vegetable bins, plastic containers, the door or the bottom of the refrigerator. This is a major vaccine no-no. The temperature in these areas will be higher than the temperature in the body of the refrigerator. Take the vegetable bins and

loc-tight plastic containers out of the refrigerator. Also, don't store vaccine on the bottom of the refrigerator. The refrigerator motor is there, and it's the warmest location in the refrigerator. Place the vaccines on the shelves in open, labeled containers, so that air can circulate around the vaccine. And, remember, don't store vaccine in the refrigerator or freezer doors because the temperature will fluctuate.

Number 8: No emergency plans for a power outage or natural disaster. Every practice should have a written Disaster Recovery Plan. The most important item in this plan is to identify a location with a backup generator to take your vaccine to in the event of a power outage or natural disaster. Consider contacting your local hospital, Red Cross, elder care facility and contact them now! An example of a mock Disaster Recovery Plan is available on the NIP broadcast resource website - you can just fill in the blanks. What you want to do is pre-arrange everything that way, when you take vacation, your backup person - remember the backup person? - will know what to do.

Number 7: Discarding multi-dose vials after they are opened for 30 days. This issue has been around for years. All multi-dose vials of vaccine have preservatives in them. Unless you see contamination in the vial, the vaccine should be used until the expiration date.

Number 6: Leaving the refrigerator or freezer door open overnight. This baffles me. In all my years, I've never left my home refrigerator or freezer door open overnight. Yet this happens every week in an office. To prevent this, check the seals on the doors, and if there is ANY indication the door seal may be cracked or not sealing properly, have it replaced. The cost of replacing a seal is much cheaper than the cost of replacing a box of pneumococcal conjugate or varicella vaccine.

Number 5: Storing varicella vaccine in a dorm-style refrigerator. Varicella must be stored in a refrigerator with a separate freezer door. No matter how hard you try to adjust the temperature to +5 F in a dorm-style refrigerator's freezer, there is no possible way to keep the refrigerator portion between 35 - 46 F! I've seen the freezer section enclosed with in everything from aluminum foil to cardboard. It doesn't keep the freezer section frozen. BUT you WILL freeze the vaccine in the refrigerator.

Number 4: Recording temperatures once per day. Temperatures fluctuate throughout the day. Temperatures in the refrigerator

and freezer should be checked at the beginning of the day to determine if the unit is getting too cold overnight and at the end of the day to determine if the unit is not holding a constant temperature throughout the day. This is an all-inclusive temperature log. Note that is has space for refrigerator temperatures AND freezer temperatures, to be documented twice per day. Some temperature logs also have a space for room temperature. This is good information to know if there is a problem with the refrigerator. Also note that the correct temperature range is noted on the temperature log: 35 to 46 F or 2 to 8 C for the refrigerator, and colder than +5 F or -15 C for the freezer.

Number 3: Recording temperatures for only the refrigerator or freezer. If your facility administers varicella vaccine, you should have a thermometer in the refrigerator AND the freezer. That means two thermometers. Not one thermometer that you can move from refrigerator to freezer and back, but two thermometers. Here are examples of calibrated, certified accurate thermometers. Rather than buying a cheap thermometer that doesn't accurately measure the temperature six months after you purchase it, consider a quality thermometer that will last for years.

Number 2: Throwing away temperature logs at the end of every month or year. It's important that you keep temperature logs for 3 years. As the refrigerator ages, you can track recurring problems. If temperatures have been documented out of range, you can determine how long this has been happening and take appropriate action. It's also a great way to prove to your boss you need a new refrigerator!

And the Number 1 Storage and Handling faux pas is: Documenting out of range temperatures on vaccine temperature logs and not taking action. Documenting temperatures is not enough. Processing the information is just as - or even more important! Your job is not done if you document 28 F consistently in the refrigerator. This temperature log shows the correct temperature range to be 35 to 46 F. Here are some hints on what you should do if the temperature is out of range. To begin with, notify your supervisor. Someone else should be aware of the problem. Attempt to adjust the thermostat. Check the condition of the unit for problems. Are the seals tight? Is there excessive lint on the coils? After you have made the adjustment, document the date, time, temperature, what the problem was, the action you took, and the results of this action. Recheck the temperature every two hours. Call maintenance or a repairman if the temperature is

still out of range. And move contents to your designated location, which will be found in your Disaster Recovery Plan.

Those are the Top Ten vaccine storage and handling errors. We've now come full circle. See how everything fits together?

ATKINSON:
The final item on the pre-encounter checklist relates to emergency preparedness. Unfortunately, we can't eliminate all unexpected events. So it becomes crucial to plan and prepare for emergencies. We all want to perform flawlessly when an emergency occurs, and a familiar, practiced plan helps that happen.

There are a variety of emergency situations that can arise in a day in the life of an office or clinic. Storms and other natural disasters can damage your facility or knock out your power. You should have a contingency plan for this sort of situation, particularly loss of power. Protecting your vaccine supply should be a high priority.

Then there are medical emergencies. Anything can happen in a medical provider's office, from heart attacks to delivery of babies to injuries. For this program we will forego a discussion of emergency C-section and focus on two office setting emergencies that could be vaccine related - syncope and allergic reactions.

Prevention of an emergency is the first consideration in developing an emergency plan. Screening for allergies and reactions following prior vaccine doses can prevent an emergency from occurring. We will discuss screening for contraindications and precautions later in the program.

Serious allergic reactions are very uncommon following vaccination, but syncope is not uncommon. Judy, could you talk about syncope?

SCHMIDT:
I'd be happy to. Syncope is a sudden loss of consciousness, commonly known as a vaso-vagal response, or fainting.

Syncopal episodes are rare in infants and young children, they are most common in older children and adolescents. Every person who has given vaccines for a few years has seen a 200 pound high school tackle faint after receiving a shot. Serious injury can result from a syncopal episode, including broken bones, head trauma, and brain injury.

One way to prevent a syncope related emergency relates to the patient's posture or position during vaccine administration. Infants and young children are usually held by a parent or sitting during their immunizations. It's a good idea for older children, adolescents and adults to sit during vaccination. Sitting during vaccine administration may either prevent syncope or prevent an injury caused by a fall.

Most syncopal episodes occur less than 5 minutes after vaccine administration, and nearly 90 percent occur within 15 minutes. As a result, you should consider observing older children, adolescents, and adults for 15 to 20 minutes after vaccination, if possible.

Office staff should be aware of and watch for warning signs that syncope could occur - a patient who is highly anxious, pale, or perspiring. If you think a syncopal episode is about to occur- or has occurred- have the patient lie down and elevate his or her legs 10 to 12 inches. Make sure the person's airway is open. People who experience a syncopal episode should be observed until their symptoms resolve.

Just a reminder- a syncopal episode is NOT a contraindication for future doses of the vaccine. Syncope is NOT an allergic reaction. If indicated, the person should receive subsequent doses on schedule.

Another potential vaccine related emergency is a severe allergic reaction or anaphylaxis. Severe allergic reactions are rare, but you need to be prepared to deal with it should it occur. Donna, could you give us details about emergency preparation for allergic reactions?

WEAVER:
Yes I will, Judy. You're right- anaphylactic reactions following vaccination are very rare when people are screened appropriately. It's critical that a vaccination provider be aware of their patient's allergies to components of the vaccine such as gelatin, eggs, or an antibiotic. The components of each vaccine are listed in the package insert that comes with the vaccine. So if you discover that a person has had a severe allergic reaction to egg, you could look through all the package inserts of vaccines you intend to administer that day, and look for ones that contain egg protein. Or, you could do this an easier way.

Here is a table that lists vaccine components, and lists which

vaccines contain that component. The table was published by the company Facts and Comparisons in their monograph called Immuno Facts. Facts and Comparisons agreed to allow us to distribute it from the National Immunization Program website. It's a valuable tool when a patient reports an allergy to a specific substance that may be included as a minor component of a vaccine. You should definitely have a copy of this table in your office.

Of course, it's possible that there can be allergies unknown to the patient or provider until symptoms are experienced. When a reaction unexpectedly occurs, EARLY detection of allergic symptoms and management of anaphylaxis can be lifesaving.

When the symptoms of facial flushing and edema, hives, swelling of the mouth, wheezing, and shortness of breath begin, immediate recognition and treatment may avoid a more severe and life threatening reaction. It sounds simple, but when the flushed face of an upset, crying child becomes more than expected, the child may, in fact, be in the initial stages of an allergic reaction. The facial flushing may increase and progress to facial edema, wheezing, and shortness of breath.

When office staff perform their regular review of the emergency plan, it's also an opportunity to be sure the emergency contact information is current. Emergency phone numbers should be posted on or near each telephone and kept up to date. The staff responsible for calling emergency assistance should know what to say and how to describe their office location. Emergency response personnel tell us that time spent in finding a provider's office inside of a building can be critical. It's very beneficial to assign a staff member the responsibility of meeting ambulance personnel at the building entrance, and securing an elevator. All office personnel should have current CPR certification, and know where the emergency equipment is located.

Judy, will you tell us more about emergency equipment?

SCHMIDT:
Sure Donna. Every office should have an emergency kit, and it should be inspected periodically to be sure it's up to date and functioning properly.

Emergency kits come in many sizes and shapes. Every office should have an emergency kit or box of equipment that is kept in a specific, centrally located place. The equipment should be placed in the box in a way that is easily seen and retrieved.

What should be in your kit? An important piece of equipment is the oral airway. More than one size of airway should be in the emergency box. The sizes and number of airways depend upon the provider's patient population. For example, a pediatric office will most likely have a fewer number of airway sizes than a Family Practice office that sees patients of a greater range of sizes.

One or more resuscitation bags should be included depending upon the ages of the patient population. A demonstration on how to use the equipment given by the vendor representative or other expert along with regularly scheduled practice is vital. A stethoscope and blood pressure cuff should be in the emergency equipment supply along with ammonia capsules, and at least three syringes, needles, and some alcohol swabs. Your kit should contain emergency drugs, particularly epinephrine and diphenhydramine. Some emergency kits include these medications in prefilled syringes supplied by the manufacturer.

Epinephrine is administered SUBCUTANEOUSLY in a limb opposite the immunization site and is usually massaged after injection to promote absorption. The dose is determined by either the body weight or age of the person. It's helpful to have a table in your kit that lists these dosages. The dose can be repeated in 10 to 20 minutes if indicated by symptoms.

Diphenhydramine hydrochloride, commonly known by it's brand name of Benadryl, may shorten an allergic reaction. But its effect is delayed rather than immediate. Depending upon the severity of the symptoms, it may or may not be useful. Diphenhydramine hydrochloride is also given by body weight.

One final point concerning emergency preparation. No matter how well a protocol is written, it's helpful only when office staff are well prepared and ready to act. Office staff should keep their CPR certifications current. Emergency procedures should be reviewed periodically, and training updates provided to staff. Documenting training in a personnel folder may be helpful in promoting staff competency. Of course, training new staff in the office emergency plan is critical, and should be part of their orientation. Severe allergic reactions are rare events. But because they can be fatal if not managed properly, your staff must be ready to respond.

ATKINSON:
Excellent advice. Thanks Judy. We will be back to discuss immunization encounter activities in just a moment.

[UNSCRIPTED VIDEO PROMO]

ATKINSON:
That video, "Ice, Champagne and Roses," is an excellent refresher on vaccine storage and management. The tape was originally produced by the California Immunization Program, then revised by the Minnesota Immunization Program to include information on newer vaccines, such as DTAP, hepatitis A, and varicella. You can order a copy of the tape from the National Immunization Program website. If you didn't catch the address, it will be listed on our broadcast resources website.

In this segment of the program we will discuss activities that occur during the immunization encounter- while the person is in the office or clinic. The critical issues during the encounter phase include screening- primarily for contraindications and precautions to vaccination, patient and parent education, vaccine administration, and after-care instructions. We will discuss each of these issues, beginning with screening.

ATKINSON:
Screening is an important part of the immunization encounter. This activity should include eligibility screening as well as medical screening. If your office or clinic is enrolled in the Vaccines for Children Program, or VFC, then it's important to screen children and adolescents for VFC eligibility.

Children, birth through 18 years of age, are eligible for VFC vaccines if they are: eligible for Medicaid; or have no health insurance; or are Native American or Alaska native. Children who ave health insurance, but immunization is not a covered benefit are eligible if they go to a Federally Qualified Health Center. Depending on your state immunization program, other children may also qualify.

There's a VFC eligibility screening form that should be completed by the parent and kept as part of the child's permanent medical record. This is what it looks like. This eligibility form does not need to be completed at each visit, but should be updated if there are any changes in the child's eligibility. If you have questions about a patient's eligibility, then we recommend that you contact your state immunization program for clarification.

There is also general information about the VFC program for both parents and providers available on the NIP website.

Another important aspect of patient screening is screening for contraindications and precautions to vaccination. Donna, would you tell us more about medical screening?

WEAVER:
Bill, not only does thorough screening provide an opportunity to prevent possible adverse reactions, but it also provides an opportunity to build rapport with the patient and parent, address their concerns, and answer any questions.

The first information you will want to obtain is the patient's prior immunization history. This information should be located on one page in the patient's medical record. If not, encourage parents or patients to bring their personal record so that you can include this information in each person's chart.

A verbal history of previous immunizations is not sufficient evidence. You should accept as valid only immunizations that are documented in writing and dated.

If a written record isn't immediately available, we recommend that you consider giving the vaccines that are indicated at that visit based on the person's age. This avoids a missed opportunity while the patient or parent continues to search for the immunization records.

Once you have the immunization history, it's time to screen for medical contra- indications or precautions. When the setting allows, we recommend that you provide patients or parents with the screening questionnaire, and the Vaccine Information Statement, or VIS, while they are waiting to be seen. The VIS includes information that will help the patient or parent respond to questions on the screening form. We'll talk more about VISs in a few minutes.

The key to reducing the risk of a serious adverse reaction is SCREENING. Every person who administers vaccines should screen EVERY patient for contraindications and precautions before giving the shot. Effective screening isn't difficult or complicated. It can be accomplished with just a few questions.

Many states have developed screening questionnaires for use in their clinics. You can develop your own sheet, or you can adapt one that has already been developed. The Immunization Action Coalition has developed a good one page screening sheet for children and another for adults.

It's important for you to understand the reasons for the questions on the screening form. We asked Doctor Deborah Wexler, Executive Director of the Immunization Action Coalition, to review the screening form with us, and explain the rationale for the questions.

WEXLER:
The key to reducing the risk of a serious adverse reaction is to identify contra indications and precautions to vaccination BEFORE giving the shot. Contraindications to vaccination can change from one dose of a vaccine to the next dose. So everyone should be screened prior to EVERY dose, even if they were screened during a prior visit. Screening for contraindications and precautions isn't difficult or complicated. This is the screening form we developed for children and teens. We suggest you use a standardized screening form like this one, so you ask the same questions every time. Let's go through the 9 screening questions and talk about why you are asking them.

ANNOUNCER:
Is the child sick today?

WEXLER:
The first question addresses whether the child has a moderate or severe acute illness, which is a precaution to vaccination. If the child has been examined, this question may not be necessary, or already may have been answered. There's no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. But with moderate or severe acute illness, vaccines should be delayed until the illness has improved. This avoids confusing a symptom of the illness - such as fever - with a vaccine adverse event, or vice versa. Mild illnesses, such as otitis media or an upper respiratory infection, are NOT contraindications to vaccination. Nor is taking antibiotics a reason to withhold a vaccine in a person who is otherwise not very sick.

ANNOUNCER:
Does the child have allergies to medications, food, or any vaccine?

WEXLER:
A severe allergic reaction to a vaccine or vaccine component is a contraindication to subsequent doses of that vaccine, or to a vaccine containing that component. An anaphylactic reaction to eggs is a contraindication to influenza vaccine, and an

anaphylactic reaction to yeast is a contraindication to hepatitis B vaccine. We suggest you inquire about allergies in a generic way, rather than read the parent a list of every component of every vaccine. Most parents won't recognize most of these components names anyway. But they WILL know if the child has ever had an allergic reaction severe enough to seek medical attention, which is what you're getting at. If you do identify a person who has had a severe allergic reaction to a product that may be in a vaccine, the next challenge is to figure out which vaccines might contain that product. To make this task easier, you need a listing of vaccine contents. A comprehensive table of vaccine components is available free from the National Immunization Program website. Remember that a local reaction, such as redness or swelling at the site of injection, is NOT a contraindication to subsequent doses of that vaccine.

ANNOUNCER:
Has the child had a serious reaction to a vaccine in the past?

WEXLER:
This open ended question is intended to identify allergic reactions following previous vaccine doses. It can also help identify conditions following pertussis vaccine. Under normal circumstances, vaccines are deferred when precautions are present. But situations may arise when the benefit of the vaccine outweighs the risk. For instance, a child who had a temperature of 105 following a prior dose of DTP or DTAP might still be vaccinated if there were an outbreak of pertussis in the community.

ANNOUNCER:
Has the child had a seizure or a brain problem?

WEXLER:
DTAP is contraindicated in children who have a history of encephalopathy within 7 days following whole cell DTP or DTAP vaccine. An undiagnosed neurologic problem is a precaution to the use of DTAP. For children with a STABLE neurologic disorder, including seizures, unrelated to vaccination, or for children with a family history of seizure, you should vaccinate as usual. In these children, you should consider the use of acetaminophen or ibuprofen to minimize the fever.

ANNOUNCER:
Does the child have cancer, leukemia, AIDS, or any other immune system problem?

WEXLER:
Live virus vaccines, such as MMR and varicella, are usually contraindicated in persons with severe immunodeficiency. However, MMR and varicella are recommended for persons infected with HIV who do not have evidence of severe immunosuppression. Varicella vaccine is contraindicated in persons with cellular immunodeficiency, but may be administered to persons with humoral immunodeficiency. All inactivated vaccines may be given to immunosuppressed persons, although the response to the vaccine may be suboptimal. Also remember that having an immunosuppressed person in the household is NOT a contraindication to vaccination of a healthy child.

ANNOUNCER:
Has the child taken cortisone, prednisone, other steroids, or anticancer drugs, or had x-ray treatments in the past 3 months?

WEXLER:
High daily doses of corticosteroids for more than 14 days can cause significant immunosuppression and increase the chance of an adverse reactions following a live vaccine. Live vaccines should not be administered for at least one month following prolonged high-dose steroid therapy, or for at least 3 months following cancer chemotherapy.

Persons receiving aerosolized steroids, such as inhalers for asthma, topical preparations, or low or moderate daily or alternate- day doses of steroids for fewer than 14 days can receive live vaccines during treatment. For those receiving high dose daily or alternate day courses for fewer than 14 days, the American Academy of Pediatrics recommends that live vaccines be deferred until steroid therapy is discontinued. Similar to other immunosuppressive conditions or therapies, inactivated vaccines may be administered to a person receiving high dose steroid therapy, although the response to the vaccine could be reduced.

ANNOUNCER:
Has the child received a transfusion of blood or blood products, or been given a medicine called immune or gamma globulin in the past year?

WEXLER:
Passively acquired antibody may reduce the effectiveness of MMR and varicella vaccines. MMR and varicella vaccines generally should not be given to people who have recently received antibody containing blood products. Depending on what product was administered, and the dose, it may be necessary to defer MMR and

varicella vaccines for up to 11 months after the blood product. The 2002 General Recommendations on Immunization includes a table that lists the most commonly used antibody containing preparations in the United States. It also lists the recommended waiting period between the blood product and administration of MMR or varicella vaccine. Every office should have a copy of this table, which can be obtained from the National Immunization Program. This question might also uncover unreported illnesses that might not have been revealed in earlier questions, since blood products are usually given for specific indications.

ANNOUNCER:
Is the child or teen pregnant, or is there a chance she could become pregnant during the next month?
WEXLER:
This question should be asked of all women of child bearing age, including young adolescents. MMR and varicella vaccines are contraindicated shortly before and during pregnancy due to the theoretical risk of virus transmission to the fetus. Sexually active women who receive MMR or varicella vaccine should be instructed to practice careful contraception for one month following receipt of either vaccine. Inactivated vaccines generally may be given to pregnant women when indicated. On the other hand, it's not necessary to inquire about pregnancy in household contacts. Having a pregnant woman living in the household is NOT a contraindication to administration of ANY vaccine to other household members.

ANNOUNCER:
Has the child received any vaccinations in the past 4 weeks?

WEXLER:
The intent of this last question is to identify persons who recently received a live virus vaccine. The Advisory Committee on Immunization Practices recommends that two live virus vaccines not given on the same day be separated by at least 28 days. If the vaccine given recently was an INACTIVATED vaccine, such as DTAP or hepatitis B vaccine, it's not necessary to defer ANY vaccine. In addition to the child and teen screening form, we have also developed a screening form for adults. It contains the same questions that are on the child and teen form, except for the question about a history of seizures. The seizure question is included on the child and teen form to identify potential precautions for pertussis vaccine. Since pertussis vaccine is not given to people older than 7 years of age, it isn't needed on the adult form.

Both these screening forms, as well as other vaccine related material for providers and patients are available free from the Immunization Action Coalition website. But whether you use our form, or some other form, the important thing is that you to ask these questions before administering vaccines to people of any age. Your patients are depending on you to make vaccines as safe as they can be. Screening every patient is one way to do this.

ATKINSON:
Another critical component of the immunization encounter is patient and parent education. As health care providers, we know that immunizations are among the most cost effective and widely used public health interventions. We also know that no medication, not even a vaccine, is 100 percent safe or effective. As the incidence of vaccine preventable diseases is reduced, the disease threat is less visible. Public focus has changed from the risk of disease to concerns associated with the vaccines themselves. Before you administer any vaccine, you have a responsibility to discuss each vaccine's benefits and risks with the patient or parent. Judy, could you expand on this?

SCHMIDT:
Bill, risk and benefit communication between the provider and the person receiving the vaccine is essential. The cornerstone of immunization patient education is the Vaccine Information Statement, or VIS.

Every health care provider, public or private, who administers a vaccine covered by the National Childhood Vaccine Injury Act is required by law to provide a copy of the most current VIS with EACH DOSE of vaccine administered. Not only the first dose, but EVERY dose. In addition, CDC encourages health- care providers to use all available VISs, whether the National Childhood Vaccine Injury Act covers the vaccine or not. It's just good practice.

Health care providers are not required by Federal law to obtain the signature of the patient or their representative acknowledging receipt of the VIS. The VISs are not designed as informed consent documents.

Because the materials cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. You should, however, consult your agency or state immunization program to determine if there are any specific informed consent requirements.

Documentation that the VIS was given is required. Health care

providers must note in each patient's permanent medical record the date printed on the VIS and the date the VIS is given to the vaccine recipient, or their legal representative.

Every VIS is dated. The date is usually located in the corner of the second page of the document. This is the date that must be recorded in the patient's chart. VISs change periodically. Paying attention to this date also helps to ensure that your office always has the most current version of each VIS.

VISs are available in over twenty languages on the Immunization Action Coalition website. State Immunization Programs have single camera- ready, or master copies available and some private provider organizations also print and sell copies of the VISs. If patients or parents are unable to read the VISs, it's up to the provider to ensure that they have the information. This can be done by reading or paraphrasing the VISs, and confirming that they are understood. Health care providers should also encourage the patient or their representative to take the VIS home. This is important because the VIS includes information that may be needed later. This includes: the recommended schedule for that vaccine; information concerning what to look for and do after the vaccination; and what to do if there is a serious reaction. The health care provider's patient education responsibilities don't end with the Vaccine Information Statement. That's just the beginning.

Donna, will you tell us more?

WEAVER:
Sure, Judy, I would be glad to. Education involves more than telling pieces of information to someone. Education is an interactive process, an exchange of information. We need to listen, hear our patient's concerns and then be prepared to address those concerns. If you are not willing to do this, then the parent will go elsewhere for their information and elsewhere may not be a reliable source of good, scientific based information.

Let's talk about parents' vaccine information needs. Based on several recent surveys, we know that the majority of parents think positively about immunizations. We also know that many parents rely on and trust their health care provider's recommendations. As we would expect, many parents don't have experience with or knowledge about vaccine preventable diseases because we no longer see these diseases in epidemic proportions.

Many questions are generated by the vaccine education materials we provide. Parents also get information from the news media, from their friends and family, and increasingly, from the Internet. Unfortunately, some of these sources have lead to misconceptions and fears in a significant number of parents.

As health care providers, our goal should be to provide parents with the basic information that they are looking for about vaccines. Research has identified seven questions that parents need to ask about childhood vaccinations. They are: What shots will my child get this visit? Why should my child get these shots? Is there any reason I should not give my child these shots? What side effects should my child have? What should I do if my child has a side effect? What should I do if my child has a severe side effect? And, finally, When is my child's next shot?

We have a couple of suggestions that may help you respond to these questions. First, help parents prepare for the immunization encounter in advance. If possible, provide parents with information ahead of time, before the immunization encounter. This information may answer some of their questions. If you don't have the opportunity to provide parents with information before they come to your clinic or office, then consider having information available in the waiting area, like brochures, pamphlets, VISs and videos.

Our second suggestion- be prepared to respond to parents' questions and concerns. Consider doing some vaccine safety communication in- services, maybe over lunch. Staff can even role- play various scenarios based on situations that have arisen in your office or clinic.

These in-services can help to ensure that all staff have the same vaccine safety information and that there are no confusing mixed messages being given to parents. Role playing can help staff be less defensive, more empathetic to parents' concerns, and sensitive to cultural influences. Be clear who in your organization will give out VISs, who will elicit the parents' questions, and who will discuss the benefits and risks. Also remember to praise parents for doing their homework and bringing their children to be immunized. Hopefully parents will realize that ultimately you both have the same interest at heart, the health and safety of their child. Bill?

ATKINSON:
Thanks, Donna. There are several excellent patient education resources available to you, including websites, videos, books,

and information sheets for your office. We also have a video devoted solely to vaccine safety and risk communication that you may want to consider for staff orientation and training. More information on all these resources is included on the broadcast resources web page.

ATKINSON:
Appropriate vaccine administration is critical to vaccine effectiveness. The recommended site, route and dosage for each vaccine are based on clinical trials, practical experience and theoretical considerations. Vaccines may not protect your patient if they are administered incorrectly. If the wrong site or needle length is used to administer a vaccine, there may be an increased risk of a local adverse reaction. So an education plan that includes competency based training on vaccine administration should be considered for everyone in your office who administers vaccines. Judy, will you get us started with some vaccine administration fundamentals?

SCHMIDT:
Thanks, Bill. Delivering vaccine into the appropriate tissue promotes optimal antibody response to a vaccine and reduces the risk of local adverse reactions. So let's talk a little more about route, site and needle length.

This is a list of vaccines that should be administered by the subcutaneous route. Those vaccines are anthrax; inactivated polio; Japanese encephalitis; measles, mumps and rubella-containing vaccines; meningococcal; pneumococcal polysaccharide; varicella; and yellow fever.

This is a list of vaccines that should be administered by the intramuscular route. Vaccines given IM include diphtheria, tetanus and pertussis- containing vaccines; Haemophilus influenzae type b; hepatitis A; hepatitis B; inactivated polio; influenza; pneumococcal conjugate; pneumococcal polysaccharide; rabies and typhoid Vi.

Inactivated polio and pneumococcal polysaccharide vaccines are listed on both tables because they can be administered by either the subcutaneous route or the intramuscular route. Neither the vaccine manufacturer nor the ACIP recommends one route over the other for either vaccine. With IPV and pneumococcal polysaccharide, it's the clinician's choice.

Subcutaneous injections are administered into the fatty tissue found below the dermis and above muscle tissue. Subcutaneous

tissue is present all over the body. The usual subcutaneous sites for vaccine administration are the thigh and the upper outer triceps of the arm. The upper outer triceps area can be used to administer subcutaneous injections to infants. The recommended needle size for subcutaneous injections in all age groups is a 23- to 25-gauge 5/8 inch needle. A longer needle could penetrate the muscle, particularly if given at an incorrect angle. To avoid reaching the muscle, the fatty tissue is pinched up and the needle is inserted at a 45-degree angle. A more perpendicular approach is used for IM injection.

The majority of vaccines administered by injection are given by the intra muscular route. Incorrect intramuscular technique can reduce vaccine effectiveness and increase local adverse reactions, so proper technique is critical. Intramuscular injections are administered into muscle tissue below the dermis and subcutaneous tissue. The amount of overlying subcutaneous tissue depends on the person and the site. Although there are several IM injection sites on the body, the recommended IM sites for vaccine administration are the vastus lateralis muscle in the antero-lateral thigh and the deltoid muscle in the upper arm. Injection at these sites reduces the chance of involving neural or vascular structures. The site depends on the age of the person and the degree of muscle development. The deltoid muscle is most commonly used in older children and adults. The deltoid muscle can be used in toddlers if the muscle mass is adequate. It's important to use anatomical landmarks to locate the site so that the injection is given into the center of the muscle. The buttock should NEVER be used to administer vaccines, although it can be used to administer large doses of immune globulin. Injection in the gluteus risks damage to nerve tissue. The recommended needle for intramuscular injections is 22 to 25 gauge. The needle length must be adequate to reach the muscle and is based on the size of the individual. The recommended needle length for an infant is 7/8 to 1 inch. The recommended needle length for toddlers and older children is a 7/8 to 1 and one-fourth inch. Adults will typically need a 1 to 1 and a half inch needle. To avoid injection into subcutaneous tissue, the skin of the selected site can be spread taut between the thumb and forefinger, isolating the muscle. Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle. The needle should be inserted fully into the muscle at a 90-degree angle.

There are a few other issues related to vaccine administration that seem to generate a lot of questions. Donna, could you review these issues?

WEAVER:
Yes, Judy, I will. We do receive a lot of questions about vaccine administration. Many of them concern infection control.

Handwashing is recommended between each patient. When working at a site where it's not feasible to wash your hands before each patient, an alcohol-based waterless antiseptic can be used between patients and in situations where your hands become soiled.

Gloves are not mandatory for vaccine administration unless there is the potential for exposure to blood or body fluids, the person giving the shot has open lesions on the hands, or it is an agency policy. But remember, gloves cannot prevent a needle- stick injury.

In November 2000, to reduce the risk of needle-stick injury and the potential for blood-borne diseases acquired from patients, the Needle- stick Safety and Prevention Act was signed into law. The act directs the Occupational Safety and Health Administration, better known as OSHA, to strengthen its existing bloodborne pathogen standards. Those standards were revised and became effective in April 2001. These federal regulations require use of safer injection devices and documentation of injuries caused by medical sharps. They also require nonmanagerial staff involvement in the evaluation and selection of safer devices before they are purchased. Needle- shielding and needle- free devices that may meet these OSHA requirements for vaccine injections are available and are listed on several websites. We will include these websites on the broadcast resource web page.

Of course, you should never EVER detach, recap or cut a used needle before disposal. All used syringe and needle devices should be placed in puncture proof containers to prevent needle sticks and reuse. Empty or expired vaccine vials are considered infectious medical waste and should be disposed of according to state regulations.

Here are a few more points about vaccine administration. It's not necessary to change the needle between reconstitution or drawing the vaccine and administering it unless the needle is contaminated or bent. Modern steel needles are not dulled by entry into a vaccine vial.

When administering multiple vaccines, NEVER mix vaccines in the same syringe unless they are approved for mixing by the Food and

Drug Administration. Very few vaccines are approved for mixing. Those that are will be packaged together or indicated in the package insert. Use a new syringe and needle to draw up each vaccine to be administered.

If more than one vaccine is to be administered in the same limb, the injection sites should be separated by at least an inch, if possible. This separation allows any local reactions to be differentiated. Vaccines that contain tetanus and diphtheria may cause more soreness than other vaccines, so you may want to give this vaccine alone or in the limb with a subcutaneous injection.

Aspiration is the process of pulling back on the plunger of the syringe prior to injection to ensure that the medication is not injected into a blood vessel. Although this practice is advocated by some experts, and most nurses are taught to aspirate before injection, there is no evidence hat this procedure is necessary. If your procedure includes aspiration and blood appears, the needle should be withdrawn, and a new site selected.

Many people, particularly health care providers, claim to have latex allergies. Latex allergy is most often a contact- type allergy. There has only been one published report of an anaphylactic allergic reaction following vaccine administration in a patient with known severe allergy to latex. A person with an anaphylactic allergy to latex should not generally receive vaccines supplied in vials or syringes that contain natural rubber, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. People with latex allergies that are not anaphylactic allergies, such as contact allergy to latex gloves, can be vaccinated with vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex.

With the number of injections that we are giving in immunization practice today, both health care providers and parents are concerned about adequate pain control. Comfort measures and distraction techniques may help children cope with the discomfort associated with vaccination. Remember that pain is a subjective phenomenon influenced by multiple factors including a person's age, anxiety level, previous health care experiences, and culture. A variety of measures ranging from topical anesthetics to diversionary techniques are discussed in both the recently updated ACIP General Recommendations on Immunization, and a vaccine administration document available on our broadcast resource website. Bill?

ATKINSON:
Donna, just to clarify this issue- does ACIP recommend that providers aspirate or not aspirate before injection?

WEAVER:
Bill, ACIP doesn't recommend anything about aspiration. Without data indicating the need for aspiration, ACIP is basically leaving this decision to the person giving the vaccine.

ATKINSON:
OK. Thanks Donna. Judy, we've talked about administering the vaccines, now what about after the shots?

SCHMIDT:
Bill, care of patients after the shots and instructions for patients and parents are an important part of the vaccine administration process. We have already discussed safety measures to avoid injury if someone faints and emergency procedures should an allergic reaction occur. Let's discuss after-care instructions. We recommend that you go over these instructions and provide a written copy BEFORE the vaccines are administered. It's unlikely that patients who have just received injections or parents who are trying to comfort a child are able to concentrate on after- care instructions.

Here is an example of written after- care instructions. This document was produced by the Immunization Action Coalition and the California Department of Health Services. You can find these instructions on the broadcast resource web page.

Parents should be prepared to give their child a little extra TLC and patience after immunization. Young children need reassurance that everything is all right, and parents are encouraged to cuddle and soothe their baby. An infant may also be comforted by a bottle, pacifier or breast feeding. Older children often respond positively to hugs, praise and little rewards.

Some vaccines can cause discomfort for a few days after the shots are given. Children- and adults- may be fussy, experience some redness, warmth, and tenderness at the injection site and have a low grade fever following vaccination. MMR and varicella vaccines may cause a rash or fever about a week after vaccination. The Vaccine Information Statement for each vaccine will tell parents and patients what kind of adverse reactions to expect. Encourage patients and parents to take the VIS home with them.

Parents should be instructed on how to manage fever and pain that

may occur following vaccination. Either acetaminophen or ibuprofen can be given if necessary. Aspirin should NEVER be given to a child because of the risk of Reye Syndrome.

Other things the parent can do if the child has a fever include giving plenty of fluids to drink; dressing the child in light clothing, and not covering or wrapping the child tightly. The parent can also sponge the child in a few inches of lukewarm water. If the patient's arm or leg is swollen, warm and red, they can wet a clean washcloth with cool water and place it on the tender area to ease the discomfort. Let the parent know that the child may not eat as much as usual for the next day or two, but not to be alarmed as long as an adequate amount of fluids are tolerated.

Parents also should be given clear instructions about when to contact the health care provider. Parents should call if the child is fussy for more than 24 hours; has a rectal temperature of 105 degrees Fahrenheit or higher; is pale or limp; has been crying continuously for more than 3 hours; if the crying isn't normal, like a high-pitched cry; if the child is shaking, twitching or jerking; or if the parent has any other concerns about the way the child looks or acts.

Serious adverse events following vaccination occur infrequently, but minor events, such as pain and redness at the injection site re common. Good after care instructions will prepare the parent, reduce their anxiety, and reduce the number of telephone calls you need to handle. Bill?

ATKINSON:
Thanks, Judy. We will be back to talk about post encounter activities after this brief pause.

[UNSCRIPTED VIDEO PROMO]

ATKINSON:
That clip was from a video on vaccine administration produced by the California Immunization Program. It's called Immunization Techniques - Safe, Effective, Caring. The video is 35 minutes long and covers all aspects of vaccine administration, including reconstitution and drawing vaccine, anatomic sites, needle length, administration techniques, and more. The video includes presenter's notes, a skills checklist, immunization site maps, and other materials. It's a great competency-based training tool for your office. The video and associated material cost 25 dollars. It's available from the California Distance Learning

Health Network, and from the Immunization Action Coalition. We have a link to this excellent package on our broadcast website. We will give you that address in a few minutes.

Now we are ready to move to the Post- Encounter Phase of the Immunization Encounter. Let's look at activities for you to consider. Documentation and record- keeping and vaccine adverse event reports. We frequently receive questions about required documentation, record maintenance and how to report adverse events. We're going to spend the remainder of our time discussing these topics. But first, let's review OTHER post- encounter activities. Clinic clean-up and medical waste disposal. It's important for you and other staff to be knowledgeable about OSHA guidelines regarding infection control and waste disposal. Adequate clinic supplies. Take time to restock your materials and supplies so that you won't be caught short during your next immunization encounter. Patient recall. We strongly recommend that you contact patients who missed their appointment to reschedule. Quality assurance and improvement activities typically include peer and record reviews. There is information on our resource web page about a software program called Clinic Assessment Software Application, better known as CASA. CASA is a software package that can help with your quality assurance by measuring vaccination coverage in your pediatric population.

ATKINSON:
Documentation and record keeping is a critical post encounter activity. A medical record is the backbone of a patient care plan. Healthcare providers need access to information about a person's medical history and vaccination status before immunizations are scheduled and given. Accurate documentation allows timely immunizations and helps prevent unnecessary disease. A complete list of past immunizations also avoids the cost and inconvenience associated with over- immunization and laboratory testing.

Judy, tell us more about maintaining immunization records.

SCHMIDT:
Bill, there are TWO immunization records that providers should maintain- the record in the office medical chart, and the record held by the person being vaccinated. The information that should be included on these records is similar. Let's talk first about the office immunization record.
An immunization record is considered part of the person's permanent medical record and should be maintained as part of each patient's chart. The immunization record should be located in the

FRONT of the patient's chart for quick review at each visit. Providers report that by simply keeping documentation on one record placed at the front of the chart, vaccine coverage improves and missed opportunities are eliminated. Placing the immunization record at the front of the chart avoids this crucial information being out of sight and out of mind.

When a provider sees the record, it's a reminder to review it to be sure the patient is up to date. Placing the immunization record at the front of the chart applies to everyone, from children to senior adults.

Although there may be some variation from one practice to another, or one state to another, all records- print and electronic- should include the following information: the entry begins with the type of vaccine, dose number, and dose amount. The manufacturer is noted as well as the vaccine lot number, the date the vaccine was administered, and the anatomic site and route. Finally, the name of the person giving the vaccine, the office address, and publication date of the Vaccine Information Statement should be noted. The publication date is printed on each VIS.

There is one footnote to charting vaccine lot numbers. A diluent that is licensed separately has a separate lot number that must be noted. Currently, this applies only to the combination vaccine TriHibit, because the diluent is a vaccine- DTAP, used to reconstitute Hib vaccine.

You may be wondering why the lot number of a vaccine needs to be charted at all. The answer is that if a particular lot of vaccine is ever recalled, the lot number in your chart will indicate which of your patients may need to be notified.

How long should your office retain medical and immunization records? The length of time medical records should be kept by each office or clinic varies by state. We believe immunization records should be kept indefinitely.

Donna, what about lost immunization records?

WEAVER:
Yes, we often get questions about reconstructing immunization records that are either lost or incomplete. Let's talk about incomplete immunization records first. Families change vaccine providers for a variety of reasons. This may result in one person having several medical records located in different provider

offices, with each record showing an incomplete series of immunizations. When the person's medical records are located, it's perfectly acceptable to review all dated, properly documented doses and consolidate the information into a single immunization record.

It's wise for all of us to keep a personal immunization record, separate from the office medical record. Parents need to know that a personally held record for each of their children is critical in documenting vaccines required for day care or school entry. Adults need a personally held immunization record for employment or international travel.

When a record documenting one or more immunizations is lost, the history of having the vaccine is lost. The National Immunization Program frequently receives requests for copies of personal immunization records. There is no national database of immunization records so we can't help individuals obtain their immunization histories. If the patient or parent doesn't have a personal held immunization record, you should contact other health care providers to obtain the history. Day cares or schools may also have a record of their immunizations.

If a reasonable search does not locate a record, the person should be vaccinated according to age. Administering doses that may have already been given is safe and assures protection. Serologic testing for some antigens, such as diphtheria and tetanus, can be considered. This is a good opportunity to talk about the advantages of immunization registries. Having a readily accessible, central repository of immunization records helps assure that people get the vaccines they need. Registries ultimately save time, money, and inconvenience for everyone.

We are seeing the need for registries today more than ever before. We know that nationally, 20 percent of children move by the age of two and change providers for this or other reasons. This leads to incomplete documentation in a single medical record. The childhood immunization schedule is complex. A registry can help simplify the process of deciding which vaccine is due at a visit. Parents and patients become complacent about returning for vaccination appointments when the disease rate is low. A registry can help generate reminder and recall notices for your patients who miss appointments. Finally, a registry can facilitate the exchange of vaccine information among providers and improve continuity of care.

We strongly encourage all providers to participate in a local or

state immunization registry if one is available in your area. Much more information on this topic is available on our website.

Office policies that place a priority on maintaining immunization records provide benefits to the provider staff as well as the patients. For example, patients receive the benefit of timely, age- appropriate immunization each time they visit the office. The provider practice staff benefit when they are able to demonstrate a high level of vaccination coverage among their patient population, and the satisfaction of knowing their patients are protected from dangerous diseases.

To summarize immunization record keeping: remember that a single complete immunization record in the FRONT of the chart will act as a reminder to check vaccination status of your patient at every visit, and facilitate review. All information about the vaccines administered, and the Vaccine Information Statements given to the patient should be recorded. You should retain these records indefinitely. And be sure to emphasize the need for the patient to keep and maintain their personally held immunization record.

ATKINSON:
Our last topic is vaccine adverse events and the Vaccine Injury Compensation Program. We- YOU- administer millions of childhood vaccines each year, and millions more to adults. Only a tiny fraction of these results in potentially serious adverse events. The Vaccine Injury Compensation Program, or VICP, is in place to address legal claims for these rare, but serious, events.

Judy, will you tell us more about the VICP?

SCHMIDT:
Sure Bill. The VICP is a no- fault federal compensation program. It serves as an alternative to the traditional tort legal system for resolving vaccine injury claims. VICP was established by the National Childhood Vaccine Injury Act of 1986, and began operation in 1988. It is jointly administered by the Department of Health and Human Services, the United States Court of Federal Claims, and the Department of Justice.

There are eleven specific antigens included in the Vaccine Injury Compensation Program. They are tetanus, pertussis, measles, mumps, rubella, polio, Haemophilus influenza type B, hepatitis B, varicella, and rotavirus. A combination vaccine containing any of these antigens is also covered, such as DTAP or MMR. Pneumococcal conjugate vaccine is currently covered under the broad category

of New Vaccines.

The types of injuries covered by VICP are published in a Vaccine Injury Table. Here is the most current version of the table. For each vaccine listed in the first column, there are specific adverse events named in the second column. Each of these events is associated with a time period shown in the last column. For instance, tetanus containing vaccines list the adverse event of anaphylaxis occurring within a 4 hour time frame. This means that there must be evidence that anaphylaxis caused by a tetanus containing product occurred within 4 hours of receiving the vaccine in order to qualify for this particular compensation.

When a specific vaccine injury occurs that appears on the table and meets the time criteria, there is a "presumption of cause". That means the vaccine is presumed to have caused the injury, unless the Court determines the event was due to a cause unrelated to the vaccine. If the specific injury does not appear on the Vaccine Injury Table, proof must be shown that the vaccine caused the condition or significantly aggravated a pre-existing condition.

There are specific time frames for filing a claim. The claim for injury must be filed with the court within 36 months after the first symptoms appeared. The injury must have lasted at least six months after the vaccine was given. OR the injury must have resulted in a hospital stay and surgical intervention. If a death occurs, the claim must be filed within 24 months of the death and within 48 months of the vaccine event that caused death.

In addition to the information in the table, there are detailed definitions, descriptions, and instructions that accompany the table. This information is extremely useful for health care providers as well as the person filing the claim.

There is an important point about reporting adverse events I want to mention here. The National Vaccine Injury Act REQUIRES health care professionals and vaccine manufacturers to report adverse events that appear on the Vaccine Injury Table. These adverse events should be reported as soon as possible after their occurrence.

In 1990, a reporting system was put into place to assist providers and families with this requirement. The system is called the Vaccine Adverse Events Reporting system, or VAERS. VAERS accepts spontaneous reports of all the required events. But it will also accept any event a health care professional,

patient, or parent suspects may be related to the vaccine. It's important that you understand how VAERS works and what it does. We asked Doctor Robert Pless, a vaccine safety expert in the National Immunization Program, to tell us about the system.

PLESS:
The Vaccine Adverse Event Reporting System, or VAERS is a program co-managed by the Centers for Disease Control and Prevention, and the Food and Drug Administration. I hope you will remember two important take home messages. First, VAERS is the cornerstone of efforts to monitor the safety of vaccines, and second, your contributions to VAERS are absolutely vital. VAERS is a unique surveillance system that relies most on health care providers, but also patients and parents, to report cases of adverse events that they think might be related to vaccination. The CDC and FDA continually monitor the safety of vaccines by collecting and evaluating these cases.

VAERS is really the only system in place that does safety surveillance on an ongoing basis. It is automatic, unlike a clinical trial or a study, it does not need to be set up to monitor a new vaccine. VAERS relies on reporting from the users and recipients of vaccines, so it cannot work without you!

VAERS was established in 1990 after Congress passed the National Childhood Vaccine Injury Act. VAERS merged two different systems that had been collecting case reports separately from private and public health care providers. Although, the Childhood Vaccine Injury Act mandates that health care providers report the events listed on a table of designated Reportable Events.

VAERS depends on the reporting of ALL clinically significant events, most of which are not listed on the Table of Reportable Events and are therefore voluntary. Any event that you suspect MIGHT have been due to a vaccination, or if you are not SURE but feel it is important to let VAERS know, should be reported.

Now let's talk about how VAERS works. I hope that most vaccine providers have heard of VAERS and have seen a copy of the VAERS reporting form. Almost 200,000 copies are sent each year to pediatricians, nurses and family physicians.

The form can be obtained from the VAERS website at www.vaers.org or by calling the telephone number found on every Vaccine Information Statement. The VAERS form is self-mailing and postage-paid, with the address and instructions on the back. When folded and sealed, it, in fact, becomes its' own envelope.

The completed form can, of course, be faxed to a toll free number. In addition, reporting through a secure web site is available at www.VAERS.org. This website provides excellent information about VAERS including a continuing education module. The module gives continuing education credits for physicians, nurses, and other professionals.

Once VAERS receives a report, a letter is sent out to the person who submitted it. The letter provides a thank you, the assigned VAERS ID number, and, if needed, requests additional information.

A team of nurses conducts personal follow up on all reports considered serious. This follow up is done to obtain more complete clinical information about the reported event. In addition to the VAERS form, VAERS welcomes hospital or clinic summaries or other additional medical information. The additional medical information is useful informing a complete history.

To show you how VAERS works, let me give two examples of why collecting reports that are merely suspected to be related to a vaccination, is important.

In the past, there was a concern that Sudden Infant Death Syndrome, or SIDS, was related to vaccination. When parents and physicians reported cases of SIDS within a few days of a vaccination, they thought that this close timing between the vaccination and SIDS suggested an association. Careful studies were conducted with control groups, and repeatedly showed that the risk of SIDS following a vaccination is no greater than if the vaccination had not been given. We now know that vaccines do not cause SIDS. Reports of SIDS are still submitted and followed up, but reassurance is given to parents that this tragic event was not because they had their baby vaccinated.

Now, let's examine the story of the rotavirus vaccine. Before the rotavirus vaccine was licensed in the fall of 1998, investigators did note a few cases of a bowel disorder called intussusception in both vaccine recipients and those who received a placebo. Although the rate among vaccine recipients was slightly higher, it was not significant. Therefore, the vaccine was licensed, but intussusception was included in product information among the list of reported adverse reactions.

Once the vaccine was widely distributed, VAERS began to receive adverse event case reports, including cases of intussusception. The number of cases reported relative to the number of doses distributed turned out to be high compared to what was expected.

This suggested, but did not confirm, a problem that we call a signal. Subsequent rigorous studies did confirm that the risk of intussusception was higher after vaccination, and the rotavirus vaccine was withdrawn. VAERS did its' job! The rotavirus problem was uncovered through VAERS and confirmed, and then appropriate action was taken. These stories of SIDS and Rotavirus highlight the importance of reporting events even when the person reporting may be unsure that the vaccine was responsible. Vaccine safety concerns raised by VAERS will be carefully evaluated before any action is taken.

So, as the cornerstone of the country's vaccine safety monitoring system, VAERS is always "on call" to receive case reports of any adverse event suspected to be related to any vaccine distributed.

A few important points: VAERS accepts all reports of adverse events. Events that are related, as well as those that are unrelated to vaccination, end up in VAERS. VAERS reports are screened and evaluated as they are received. Concerns are flagged and further assessed, as illustrated by the examples of intussusception and SIDS.

VAERS relies on the astute health care provider to notice and report adverse events that may be related to vaccination. VAERS is a focal point of all sorts of questions related to vaccine safety. By being that focal point, it ensures that concerns have a much better chance to be heard and evaluated. This is like when a restaurant outbreak occurs. Everyone may go to a different emergency room, but the different hospitals all call the public health department! That way the pieces are put together and the outbreak is discovered and managed.

Thank you for this opportunity to discuss the Vaccine Adverse Event Reporting System. Because in the end, it relies on you to help make sure that vaccines continue their exceptional track record of safety. The VAERS program welcomes feedback on what can be done to make the reporting process easier. And remember: when in doubt, report it!

SCHMIDT:
Now that we have reviewed the vaccine adverse event reporting system as well as the vaccine injury compensation program, it's important to remember that these are two separate systems, managed by different agencies. Filing a VAERS report is not the same as filing a vaccine compensation claim. A VAERS report is NOT a compensation claim. A compensation claim is filed separately from the VAERS report. A VAERS report may be

appropriate where a compensation claim is not. There is more information about the Vaccine Injury Compensation Program and VAERS on the broadcast resource website.

ATKINSON:
Thank you Judy. We would like to give you a few additional resources you can use to get more information about the topics we covered in today's program.

We have created a special page on the National Immunization Program website to provide one stop shopping for many of the documents and forms we have discussed today. There are also links to information on other vaccine related topics and resources. The address is www.cdc.gov/nip.

If you have questions that we didn't answer on the air, or wish to order materials and don't have Internet access you can call the National Immunization Information Hotline at 800-232-2522. The Hotline is staffed Monday through Friday from 8 AM until 11 PM eastern time.

You can use the Internet to E-mail questions, comments, or requests directly to the National Immunization Program. The address is nipinfo@cdc.gov. That Email address again: is nipinfo@cdc.gov.

Finally, if you would like to find out more about upcoming Public Health Training Network courses, visit the PHTN website at www.phppo.cdc.gov/phtn.

Thank you for joining us for The Immunization Encounter: Critical Issues. We've enjoyed bringing it to you. Please join us on August 15 for our annual broadcast of Immunization Update. We'll see you then. Goodbye.